

REMARKS

Claims 1-28 were pending in the present application. Claims 1, 7, 8, 12, and 20-28 have been canceled herein without prejudice to their presentation in another application. Claims 2-6, 9, 10, and 13-19 have been amended herein, support for which can be found throughout the specification and at, for example, page 7, lines 11-13 and 22-23 of the specification. New claims 29 and 30 have been added herein, support for which can be found throughout the specification and in original claims 18 and 19. No new matter has been added. Upon entry of the present amendment, claims 2-6, 9-11, 13-19, 29, and 30 will be pending.

As a preliminary matter, Applicants thank the Examiner for indicating that claim 18 and 19 are allowed (see, Office Action at page 1).

I. The Claims Are Clear And Definite**A. Claims 16 and 24**

Claims 16 and 24 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. The Office asserts that the phrase “cholesterol-associated tumor” is indefinite (see, page 3 of the Office Action). Although Applicants disagree, solely to advance prosecution of the present application, claims 16 and 24 have been canceled herein. Thus, rejection of claims 16 and 24 is moot.

B. Claim 12

Claim 12 is rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention (see, pages 4-5 of the Office Action). Although Applicants disagree, solely to advance prosecution of the present application, claim 12 has been canceled herein. Thus, rejection of claim 12 is moot.

C. Claim 20

Claim 20 is rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which

Applicants regard as their invention (see, page 5 of the Office Action). Although Applicants disagree, solely to advance prosecution of the present application, claim 20 has been canceled herein. Thus, rejection of claim 20 is moot.

D. Claim 11

Claim 11 is rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. The Office asserts that the “N⁶” in the first name is not correct and that the term should be “N⁶” or “N₆” (see, page 5 of the Office Action). Applicants traverse the rejection and respectfully request reconsideration because the name “N-{[4-((2R,3R)-1-(4-fluorophenyl)-3-{[2-(4-fluorophenyl)-2-hydroxyethyl]thio}-4-oxoazetidin-2-yl)phenoxy]acetyl}glycyl-N⁶-acetyl-D-lysine” is correct as written. No evidence has been provided by the Office to support its assertion.

E. Claims 1 and 2

Claims 1 and 2 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. The Office asserts that the “second species has a brace before the azetidinone, but a bracket is needed” (see, pages 5-6 of the Office Action). Applicants have canceled claim 1 and amended claim 2, thus rendering the present rejection moot.

II. The Claimed Invention Is Supported by Ample Written Description**A. Claim 20**

Claim 20 is rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (see, page 5 of the Office Action). Although Applicants disagree, solely to advance prosecution of the present application, claim 20 has been canceled herein. Thus, rejection of claim 20 is moot.

B. Claims 21-25

Claims 21-25 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (see, page 4 of the Office Action). Although Applicants disagree, solely to advance prosecution of the present application, claims 21-25 have been canceled herein. Thus, rejection of claims 21-25 is moot.

III. The Claimed Invention Is Sufficiently Enabled**A. Claims 1-10, 12-17, and 20-28**

Claims 1-10, 12-17, and 20-28 are rejected under 35 U.S.C. §112, first paragraph as allegedly failing to provide an enabling disclosure. The Office mistakenly asserts that “solvates are not enabled” (see, page 3 of the Office Action). Applicants traverse the rejection and respectfully request reconsideration because one skilled in the art would be able to practice the claimed invention without being required to perform undue experimentation.

The sole reason for asserting that “solvates” are not enabled is the Office’s assertion that the “numerous examples presented [in Applicants’ specification] all failed to produce a solvate. The evidence of the specification is thus clear: These compounds do not possess the property of forming solvates; there is no evidence that such compounds even exist” (see, Office Action at pages 3-4). Applicants’ undersigned representative is, however, unable to locate any portion of the specification where Applicants teach that a preparation of a particular solvate failed. No amount of undue experimentation is required for one skilled in the art to make and use solvates. Indeed, the Office does not even assert what experimentation is needed, let alone explain why such experimentation is undue. Thus, the Office has failed to support the position taken.

Thus, there is no reason to believe that one skilled in the art would be required to perform any amount of undue experimentation to make and use the claimed invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

B. Claims 15, 16, 23, and 24

Claims 15, 16, 23, and 24 are rejected under 35 U.S.C. §112, first paragraph as allegedly failing to provide an enabling disclosure. The Office mistakenly asserts that the “prevention and treatment of Alzheimer’s Disease and the prevention and treatment of cholesterol-associated tumors with such compounds is not deemed enabled” (see, page 6 of the Office Action). Although Applicants disagree, solely to advance prosecution of the present application, claims 15, 16, 23, and 24 have been canceled herein. Thus, rejection of claims 15, 16, 23, and 24 is moot.

IV. Obviousness-Type Double Patenting

Claims 1-10, 12-17, and 20-28 are rejected under the doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-37 of U.S. Patent No. 7,470,678 (hereinafter, the “’678 Patent”). Applicants traverse this rejection and respectfully request reconsideration because the claimed subject matter is not an obvious variant.

The Office asserts that although the conflicting claims are not identical, they are not patentably distinct from each other because “there is extensive overlap...” (see, Office Action at page 2). The patent laws require more than a mere overlap in claim scope when concluding that particular compounds are obvious variants. As stated by the Federal Circuit:

The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious.
(citation omitted)

In re Baird, 29 U.S.P.Q.2d 1550, 1552 (Fed. Cir. 1994). As stated in §804 of the M.P.E.P., the analysis employed in an obvious-type double patenting determination parallels the guidelines for analysis of a 35 U.S.C. §103 rejection, which requires analysis of the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

Further, as just stated, an obviousness-type double patenting rejection is analogous to a failure to meet the nonobviousness requirement of 35 U.S.C. §103. *In re Braithwaite*, 154 U.S.P.Q. 29, 34 (C.C.P.A. 1967) and *In re Longi*, 225 U.S.P.Q. 645, 648 n.4 (Fed. Cir. 1985). Thus, under the law, the pivotal question in an obviousness-type double patenting analysis is: Does any claim in the application define merely an obvious variation of an invention disclosed

and claimed in the patent? *In re Vogel*, 164 U.S.P.Q. 619 (C.C.P.A. 1970). If the answer to this question is no, there can be no double patenting. In making this analysis, then, the proper inquiry is as taught in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). See, M.P.E.P. §804.

The Office asserts that the last recited species of claim 17 of the '678 Patent is the species that is recited in the proviso of Applicants' claim 1 of the present application. The Office also asserts that the "first proviso species falls within the patent claim, and appears as example 25" (see, Office Action at page 2). Claim 1 of the present application, which recites the provisos referred to in the Office Action, has been canceled. Applicants also point out that the -O-CH₂-C(=O)-NH-C(R¹)-C(=O)-N(R⁶)-C(R²)(R⁵)-C(=O)OH moiety of the formula recited in Applicants' claim 2 of the present application is quite different than the corresponding moiety of -O-[C(R⁹)]_n-C(=O)-N(R¹⁰)-C(R¹¹)(R¹²)-[C(R¹³)(R¹⁴)]_m. Thus, no claim in the present application defines merely an obvious variation of an invention disclosed and claimed in the '678 Patent. Accordingly, Applicants respectfully request that the obviousness-type double patenting rejection be withdrawn.

V. Conclusion

In view of the foregoing, Applicants respectfully submit that the claims are in condition for allowance. An early notice of the same is earnestly solicited. The Office is invited to contact Applicants' undersigned representative at 610.640.7859 if there are any questions regarding Applicants' claimed invention.

The Commissioner is hereby authorized to debit any underpayment of fee due or credit any overpayment to Deposit Account No. 50-0436.

Respectfully submitted,

/Paul K. Legaard, Reg.# 38534/
Paul K. Legaard, Ph.D.

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Pepper Hamilton LLP
400 Berwyn Park
899 Cassatt Road
Berwyn, PA 19312-1183

Telephone: 610.640.7859
Facsimile: 267.430.7647